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10/551,557	10/03/2005	Christos Tsaklakidis	MERCK-2723	3824

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EXAMINER	
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In re Application of :
Tsaklakidis et al. :
Serial No.: 10/551,557 :DECISION ON PETITION
Filed: 3 October 2005 :
Attorney Docket No.: MERCK-2723 :

This letter is in response to the Petition filed under 37 C.F.R. 1.181 filed on 9 February 2009 requesting review and withdrawal of restriction requirement mailed 11 April 2008, entry of the amendment filed 16 December 2008 and withdraw of the finality of the Office action mailed 28 May 2008. The delay in acting upon this petition is regretted.

BACKGROUND

This application was filed as a national stage application in compliance with under 35 U.S.C. 371 and as such is subject to PCT unity of invention practice.

On 11 April 2008, the examiner mailed a restriction requirement in which claims 11-26 and 29-41 were divided into 3 groups, consisting of product, process of using and process of making the product. An election of species was required amongst the compounds of Formula I.

On 28 April 2008, applicant elected, with traverse, Group I and species of

the compound 1-N-[(4-chlorophenyl)]-2-N-{[4-(3-oxomorpholin-4-yl)phenyl]}-(2R,4R)-4-hydroxypyrrolidine-1,2-dicarboxamide.

On 28 May 2008, the examiner considered the traversal and made the election of species and restriction requirement final. Claims 21, 24-26, 31 and 33-42 were withdrawn from consideration as being directed to non-elected inventions. Claims 1-20, 22-23, 29-30 and 32 were objected to for reciting non-elected subject matter. Claims 1-20, 22-23, 29-30 and 32 were rejected as follows:

> Claims 1-20, 22-23, 29-30 were rejected under 35 USC 112, first paragraph for scope of enablement.
>
> Claims 1-20, 22-23, 29-30 were rejected under 35 USC 112, first paragraph for indefiniteness.
>
> Claims 1-15, 17, 29, 30 and 32 were rejected under 35 USC 102(e) as being anticipated by Bigge.
>
> Claims 111-20, 22, 23, 29 and 30 were provisionally rejected on the ground of non-statutory double patenting over claims 40-49 of copending application 11/575,711.

On 28 August 2008, applicant filed a response to the Office action.

On 7 November 2008, in a final Office action, claims 26, 31, 33, 40-42, 47-55, 58 and 59 were withdrawn from consideration as being directed to non-elected inventions. Claims 1, 23, 29-30, 43-46, 56, 57 and 60 were indicated as rejected on the PTOL 326 form. In the body of the final Office action, Claims 1, 23, 26, 29-33 and 40-60 were indicated as pending.

> Claims 1, 23, 29-30 and 32, 43-46 and 56, 57 and 60 were objected to for reciting non-elected subject matter.
>
> Claims 1, 23, 29, 30, 32, 43-46, 56, 57 and 60 were rejected finally rejected under 35 USC 112, first paragraph for scope of enablement over produg derivative and solvates.
>
> Claims 1, 23, 29, 30, 32, 43-46, 56, 57 and 60 were rejected finally rejected under 35 USC 112, second paragraph for indefiniteness for "derivative."
>
> It is unclear which claims are rejected under double patenting.
>
> The rejection under 35 USC 102 was withdrawn.

The Office action did not contain a prior art rejection. Newly added claims were included in statements of final rejection without any reasoning or analysis to show why the prior rejections were applicable to newly added claims.

On 16 December 2008, applicants filed an after final amendment which, if entered, would have removed the terms prodrug derivative and solvates from claims.

On 6 January 2009, the examiner mailed an advisory action which indicated that the after final amendment would not be entered because prosecution was limited to the elected species, withdraw of grounds of rejection would necessitate rejoinder of non-elected species which requires further search and evaluation.

On 9 February 2009, applicants filed this petition under consideration.

DISCUSSION

The petition and file history have been carefully considered.

At the onset, the following irregularities have been noted, which are useful in addressing applicant's first request, that the finality of the Office action mailed 7 November 2008 be withdrawn:

- In the restriction requirement mailed 11 April 2008, claims 1-10 were not placed into any groups. This error was apparently correctly in the next action when claims 1-10 were included in Group I for examination.

- In the non-final Office action mailed 28 May 2008, the restriction requirement only addressed Groups I and II. Group III was left out altogether, so it is unclear whether Group III is or is not restricted away from Group I or Group II.

- In the non-final Office action mailed 28 May 2008, claims 1-20, 22-23, 29-30 and 32 were objected to for reciting non-elected subject matter.

- Claim 32 was not included in the non-final rejection under 35 USC 112, first paragraph. However Claim 32 was included in the final rejection under 35 USC 112 first paragraph.

- In the non-final and the final Office action, it was incorrect to withdraw claim 40 (set forth below as pending at time of first Office action on merits) from examination as it depends upon examined claims 30, which ultimately depends from independent claim 1 and recites the elected species.

> 40. (Currently Amended): A medicament composition ~~Medicament~~ according to Claim 30, wherein said at least one compound is ~~comprising~~ 1-N-[(4-chlorophenyl)]-2-N-{[4-(3-oxomorpholin-4-yl)phenyl]}-(2R,4R)-4-hydroxypyrrolidine-1,2-dicarboxamide and/or a pharmaceutically usable derivative, solvate, salt or stereoisomers ~~derivatives, solvates, salts and stereoisomers~~ thereof, including mixtures thereof in all ratios, and at least one further medicament active ingredient is aspirin.

30. (Previously Presented): A medicament composition comprising at least one compound according to claim 1 and at least one further medicament active ingredient.

For these reasons, the finality of the Office action mailed 7 November 2008 is premature and will be withdrawn.

Second, applicants request that the amendment filed 22 August 2008 be entered. Because finality has been withdrawn, the amendment filed 16 December 2008 will be entered.

Third, Applicants request that the examiner extend the search and examination of the Markush claims. In response, it is noted that MPEP 803.02 sets forth guidance concerning the examination of examination required for Markush claims:

> In applications containing a Markush-type claim that encompasses at least two independent or distinct inventions, the examiner may require a provisional election of a single species prior to examination on the merits. An examiner should set forth a requirement for election of a single disclosed species in a Markush-type claim using form paragraph 8.01 when claims limited to species are present or using form paragraph 8.02 when no species claims are present. See MPEP § 808.01(a) and § 809.02(a). Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

All claims directed to the elected invention, as amended on 16 December 2008, will be examined following the guidance in MPEP 803.02.

Fourth, applicants wish to have the restriction requirement withdrawn. Because this application is filed as a national stage application in compliance with 35 USC 371, at each step of prosecution, the examiner should re-assess unity of invention with regard to the claims as pending and the state of the prior art.

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

When Claims Are Directed to Multiple Categories of Inventions:

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

In this application, the examiner maintained lack of unity in the Final Office action, even though there was no prior art rejection on elected product claims. This was incorrect. If the claimed product is free of the prior art, the examiner should be rejoining the first method of making and the first method of using the claimed product, per 37 CFR 1.475.

DECISION

The petition is **GRANTED** for the reasons set forth above.

The finality of the Office action mailed November 2008 has been withdrawn.

The amendment filed on 29 July 2008 will be entered.

All claims which encompass the elected species will be examined together, including claim 40.

The examiner will re-assess unity of invention with regard to the claims as pending between Group I, II and III and in each subsequent action, clarify on the record whether the Groups I, II and III are restricted or rejoined. If the same or corresponding technical feature makes a contribution over the prior art, the product, method of making and method of using with be examined together, per PCT Rules. If the elected species is allowable, the examiner will follow the practice in MPEP 803.02 and examined a second and subsequent species.

The application will be forwarded to the examiner for preparation of a non-final Office action consistent with this decision, and following the Markush examination guidelines in MPEP 803.02.

Should there be any questions about this decision, please contact Quality Assurance Specialist Julie Burke, by letter addressed to Director, Technology Center 1600, at the address listed above,

or by telephone at 571-272-1600 or by facsimile sent to the general Office facsimile number, 571-273-8300.

Remy Yucel
Director, Technology Center 1600